ART 34 AMDT

Claims (retyped)

1. A vaccine composition suitable for administration to a vertebrate host, including man, which comprises:

(a) a polynucleotide vaccine component comprising at least one polynucleotide encoding at least one antigen, such that introduction of said formulation into said vertebrate host results in expression of a biologically effective amount of said antigen or antigens so as to induce a prophylactic or therapeutic immune response;

(b) a protein antigen vaccine component comprising at least one protein antigen selected from the group of model protein antigens and vaccine protein antigens; and

(c) a mineral-based, negatively charged adjuvant,

further characterized in that said mineral-based, negatively charged adjuvant is prepared by preincubating or subsequently mixing with said at least one protein antigen vaccine component prior to formulating with said polynucleotide vaccine component.

2. A vaccine composition according to claim 1, wherein said mineral-based negatively charged adjuvant is an aluminium salt or a calcium salt.

3. A vaccine composition according to claim 2, wherein said aluminium or calcium salt is selected from the group consisting of aluminium phosphate, aluminium hydroxyphosphate, phosphate-treated aluminium hydroxide, calcium phosphate, calcium hydroxyphosphate, and phosphate-treated calcium hydroxide.

4. A vaccine composition according to any one of claims 1 to 3, wherein said group of model protein antigens range from acidic IEP proteins to alkaline IEP proteins.

5. A vaccine composition according to any one of claims 1 to 4, wherein said group of vaccine protein antigens includes a surface protein or a core protein of HBV, a de-toxified toxin from the bacteria Clostridium tetani (i. e. tetanus toxoid), a de-toxified toxin from the bacteria Clostridium botulinus (i. e. botulinus toxoid), and a de-toxified toxin from the bacteria Corynebacterium diphtheriae (i. e. diphtheria toxoid).

6. A vaccine composition according to any one of claims 1 to 4, wherein said group of vaccine protein antigens includes protein antigens derived from inactivated poliovirus.

7. A kit comprising a vaccine composition as defined in any one of the claims 1-6 in a unit dose form for administration to a vertebrate recipient, including man.

8. Use of a mineral-based, negatively charged adjuvant as a component in a combined DNA/protein-based vaccine composition as defined in any one of claims 1-6.

9. A method for preparing a vaccine composition according to any of claims 1 to 6, wherein a mineral-based negatively charged adjuvant is preincubated or subsequently mixed with at least one protein antigen vaccine component prior to formulating with a polynucleotide vaccine component.